

U.S. Application Serial No. 09/941,237  
Amendment and Response Dated December 15, 2003  
In Reply to Office Action Dated August 15, 2003

### REMARKS

Applicant affirms the election made in a telephone conversation with the Examiner on August 4, 2003, further restricting claims 26-30 as drawn to the non-elected species of custom orthodontic appliances. Applicant argues below that claim 32 is allowable and generic to these claims. Accordingly, Applicant respectfully traverses the restriction of claims 26-30 and requests that the restriction be withdrawn and the claims allowed.

Claims 31, 38-41 and 49-52 are being canceled. Claims 53-62 are added and are in the same group and species as the elected group and species claims 32-37, as set forth in more detail below.

Claims 32-36 are rejected under 35 U.S.C. §103(a) as unpatentable over Brodtkin et al. U.S. Patent No. 6,322,728 alone, and Claim 37 is rejected over Brodtkin et al. in view of Helinski, U.S. Patent No. 5,136,515. Claims 32 and 35 are additionally rejected as unpatentable over Fink et al. U.S. Patent No. 5,510,066 alone.

#### ***Response to Claim Rejections based on Brodtkin et al.:***

The Brodtkin et al. patent was not filed before the invention claimed by Applicant. The application for the Brodtkin et al. patent was filed on July 9, 1999. It cites a relation to a provisional application filed on July 10, 1998.

Applicant has submitted herewith the declarations under Rule 131 (37 C.F.R. 1.131) of inventor, Craig A. Andreiko and his counsel, Joseph R. Jordan. These declarations establish that the invention to which the claims relate was reduced to practice before July 10, 1998. Further, these declarations establish that the reduction to practice occurred June 20, 1997, which is the date of the provisional application to which U.S. Patent No. 5,975,893 to Chishti et al. is related. The Chishti et al. patent was considered but not applied in the Office Action. The facts are as follows:

The Declaration of Joseph R. Jordan authenticates Exhibits 1-6, which, along with Exhibits A-E, Dr. Andreiko describes and puts into context in his declaration.

Exhibit E is a memorandum written by co-inventor Eric Chapoulaud to Dr. Andreiko and others at Ormco Corporation in relation to the project under which the invention was made. It describes his evaluation of two embodiments of a process to make custom orthodontic appliances by depositing layers of material in connection with the ELAN project. (Patents describing the ELAN

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project of making custom orthodontic appliances are incorporated by reference into the first page of the specification of the present application and include U.S. Patent No. 5,431,562 and others.) The two embodiments of the process of making appliances by depositing layers of material include what Mr. Chapoulaud refers to as "photo-polymerizable (Stereo-lithography)" and wax (3D plotting). In Stereo-lithography, a photo-polymerizable material is deposited one layer at a time and the layer is selectively exposed to light, usually UV light with a laser. The exposure changes the material so that it can selectively harden so that some (usually the unexposed) material can be removed while other (usually the exposed) material will remain and will have the shape of a tooth, or an appliance that will fit custom against a particular tooth. In the so-called wax 3D plotting, ink or two different melting points is selectively jetted, layer by layer, to build up an object having a tooth shaped surface. The object is formed of the higher melting point wax so that the lower melting point wax can be selectively removed by heat, leaving the object. The object is used as a pattern in an investment casting process that results in the manufacture of an orthodontic appliance. In his evaluation, Mr. Chapoulaud selected a particular machine for use with the wax-printing, investment casting embodiment because it had the highest accuracy and resolution. This memorandum was written before any of the dates of the Brodtkin et al. or Chishti et al. references.

Paragraph 2 of the Declaration of Dr. Andreiko describes Exhibits 1 through 6 as illustrating a reduction to practice, before July 10, 1998, of the method of producing Elan custom orthodontic brackets by a wax-printing, investment casting method of building up layers of wax using a Sanders Model Maker machine to produce wax patterns for the investment casting of the brackets. The exhibits show the machine, the printing of the patterns, and the finished bracket products. Exhibits 1-6 are prints from photographic slides actually used in generating the drawings of the present patent application.

In paragraph 3 of his declaration, Dr. Andreiko further describes Exhibits A and B, which are pages from the laboratory notebook dated before July 10, 1998, kept by Eric Chapoulaud in producing orthodontic brackets according to the claimed invention. In paragraph 8, Dr. Andreiko states that these notes dealt with tests made with a second of two Sanders Model Maker machines.

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In paragraphs 4-8 of his declaration, Dr. Andreiko describes tests that resulted in reduction to practice of investment cast brackets using the layered wax printing method that took place prior to June 20, 1997. As noted in paragraph 7 of his declaration, the bracket shown in the dated photograph of Exhibit D was made before June 20, 1997 by the claimed method.

The method took three-dimensional tooth shape and appliance shape data to define the boundaries between two types of wax deposited in layers to build up the shape of the object to be cast.

Based on the facts discussed above, Applicant has demonstrated reduction to practice of a method of manufacturing an orthodontic appliance as claimed in claim 32, by producing digital data defining a three-dimensional surface of an orthodontic appliance and manufacturing the orthodontic appliance based on the digital data by depositing material layer by layer in a plurality of layers each constituting a two-dimensional cross section of a solid object having an edge defined by data of the three-dimensional surface, the layers being stacked in a third dimension to form the solid object having a three-dimensional surface defined by the data.

The evidence more specifically shows the reduction to practice of the method more specifically claimed in claims 34-37. Dependent claim 37 most specifically relates to the method of depositing wax of at least two types, one forming said first portion and one forming said second portion, and the deposition thereof to selectively form the layers includes the selective depositing of the portions of material in layers to define a cross section of the object with said second portion forming the pattern and being at least partially surrounded by a removable medium formed of said first portion. New dependent claims 53-62 relate to more specific embodiments of claim 32.

Based on the above, Brodtkin et al. is removed as a reference to the claims discussed. Similarly, Chishti et al. is eliminated as a possible reference. Accordingly, the claims of the present application are not unpatentable over these references.

***Response to Claim Rejection based on Fink et al.:***

Only claims 32 and 35 are rejected over Fink et al. Fink et al. relates to the general manufacturing technique referred to as free form manufacturing or rapid prototyping. Fink et al.

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makes no effort to teach whether this or any other method of manufacturing is suitable or desirable for use in making orthodontic appliances. Applicant makes no claim to having invented a method of free form manufacturing or rapid prototyping. Applicant in fact bought such machines that were developed by others.

Fink et al. does not suggest that any process they disclose is suitable for, and should be used for, the making of orthodontic appliances, not to mention how it should be used. Absent some suggestion in the Fink et al. patent or in a secondary reference to use processes of Fink et al. for orthodontic appliance manufacture, no *prima facie* case of the obviousness of claims 32 and 35 is made. Accordingly, Applicant submits that claims 32 and 35 are patentable over Fink et al.

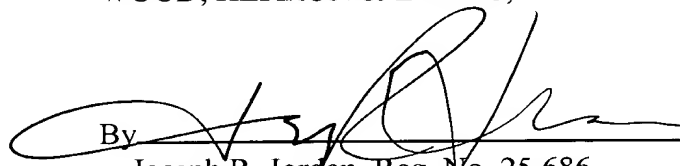
***Custom Orthodontic Appliance claims 26-30:***

One value of the method of the present invention is that it is useful for making appliances that can be made one by one. Because the manufacture is in response to digital data defining the object surfaces, the invention is most useful in making appliances that are custom. The specification discloses the invention in the context of custom orthodontic appliance manufacture. Claims 26-30, as amended, are claims that are dependent on an allowable generic claim. Accordingly, it is submitted that the restriction of claims 26-30 should be withdrawn and the claims should be allowed.

Based on the declarations, exhibits, amendments and remarks above, it is respectfully submitted that the claims, as amended, are allowable. Accordingly, an early allowance is requested.

Respectfully submitted,

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